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| 08/765,588      | 04/25/1997  | NICHOLAS KIM HAYWARD | 10441               | 6257             |

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| EXAMINER |
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SAOUD, CHRISTINE J

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1647

DATE MAILED: 06/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                       |                                       |  |
|------------------------------|---------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>08/765,588  | <b>Applicant(s)</b><br>HAYWARD ET AL. |  |
|                              | <b>Examiner</b><br>Christine J. Saoud | <b>Art Unit</b><br>1647               |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 April 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28, 30, 33, 44-47, 50, 52-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28, 30, 44-47, 50, 52-59 is/are rejected.
- 7) ☒ Claim(s) 33 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Applicant's response of 18 April 2006 has been received and entered. Claims 28, 30, 33, 44-47, 50, 52-59 are pending and under examination in the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

In response to the notice to comply with the requirements set forth in 37 CFR 41.202(a)(2)-(a)(6), Applicant has filed assignment papers such that the instant application is now assigned to Ludwig Institute for Cancer Research and Licentia Ltd. Application asserts that in light of the common ownership of the present application and the '939 patent, the basis for the proposed interference is terminated.

However, Applicant's actions necessitate the new grounds of rejection below.

### ***Claim Objections***

Claim 33 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The nucleic acid molecules of claims 44 and 45 encode specific polypeptide molecules with specific amino acid sequences. The nucleic acid molecule of claim 33 comprises a nucleotide sequence of SEQ ID NO:16, which does not encode those polypeptide molecules, and therefore, is not a proper dependent claim. However, the nucleic acid molecule of SEQ

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ID NO:16 is free of the prior art of record, and an independent claim directed to an isolated nucleic acid molecule comprising the nucleotide sequence of SEQ ID NO:16 would be allowable.

Claim 59 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The nucleic acid molecule of claim 44 encodes a polypeptide comprising SEQ ID NO:4. The nucleic acid molecule of claim 59 encodes a polypeptide comprising SEQ ID NO:6, therefore it does not further limit the claim from which it depends.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

Claims 44, 28, 30, 50 and 53 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. The claimed subject matter is covered by U.S. Pat. No. 5,928,939. For Applicant's clarification, the nucleic acid sequence of SEQ ID NO:14 of Eriksson et al. is identical to the nucleic acid sequence of SEQ ID NO:3 of the instant application over 624 bases, except for one difference (C to T) which is silent in the encoded protein. The protein encoded by SEQ ID NO:14 of Eriksson et al. is 100% identical to that of encoded protein of the instant claims (SEQ ID

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NO:4). Therefore, the nucleic acid molecule of Eriksson et al. would clearly encode a polypeptide comprising SEQ ID NO:4 as recited in claim 44. Additionally, because the proteins have the same amino acid sequence, they should also share the same biological properties, thereby meeting the limitation of claim 28. Both of the proteins are human in origin, thereby meeting the limitation of claim 30.

Claims 44, 28, 30, 50, 53 and 54 are directed to an invention not patentably distinct from claim 1 of commonly assigned U.S. Pat. No. 5,928,939. Specifically, the nucleic acid sequence of SEQ ID NO:14 of Eriksson et al. is identical to the nucleic acid sequence of SEQ ID NO:3 of the instant application over 624 bases, except for one difference (C to T) which is silent in the encoded protein. The protein encoded by SEQ ID NO:14 of Eriksson et al. is 100% identical to that of encoded protein of the instant claims (SEQ ID NO:4).

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Pat. No. 5,928,939, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions

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were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 44, 28, 30, 50 and 53 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 13 of U.S. Patent No. 5,928,939. Although the conflicting claims are not identical, they are not

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patentably distinct from each other because the nucleic acid sequence of SEQ ID NO:14 of Eriksson et al. is identical to the nucleic acid sequence of SEQ ID NO:3 of the instant application over 624 bases, except for one difference (C to T) which is silent in the encoded protein. The protein encoded by SEQ ID NO:14 of Eriksson et al. is 100% identical to that of encoded protein of the instant claims (SEQ ID NO:4).

Claims 47 and 52 are provisionally rejected under the judicially created doctrine of double patenting over claims 59-60 of copending Application No. 09/907,007. This is a provisional double patenting rejection since the conflicting claims have not yet been patented. The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The claims of '007 are directed to nucleic acids which hybridize to the complement of SEQ ID NO:3. The instant claims are directed to nucleic acids which comprise or consist of SEQ ID NO:3. The instant claims are to nucleic acids which hybridize to the complement of SEQ ID NO:3. The most obvious embodiment of the broader claims would be the nucleic acid of SEQ ID NO:3, therefore, the claims of '007 and the instant claims are directed to common subject matter and issuance of a patent to both would provide an improper extension of the "right to exclude" granted by a patent.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 44-47, 50, 52-59 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 46-49 and 59-60 of copending Application No. 09/349,954. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are directed to nucleic acid molecules encoding polypeptides, and the claims of '954 are directed to methods of making polypeptides using specific nucleic acid molecules. Such method claims of '954 were not restricted from the nucleic acid claims and it is *prima facie* obvious to use the nucleic acid which encodes the polypeptide in a method of making the polypeptide. The nucleic acids of the instant application are encompassed and used by the method claims of '954, therefore, the subject matter clearly overlaps and is not patentably distinct, absent evidence to the contrary. Additionally, '954 includes nucleic acid claims encoding SEQ ID NO:6 which is also claimed in the instant application (see claims 26 and 57 of '954 and 59 of the instant application).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

No claim is allowed.



Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**CHRISTINE J. SAUD  
PRIMARY EXAMINER**

*Christine J. Saud*